not releasing said active ingredient to any substantial extent in an oral cavity of an ingestor,

melting in a region of an ingestor's gastrointestinal tract, other than an oral cavity, having a temperature of about 30 to about 40°C, and

releasing said active ingredient in said region of melting whereby enhancing gastrointestinal absorption of said active ingredient in said region.

17. (Amended) A pharmaceutical composition according to claim 11 wherein the wax is at least one glyceride of a long-chain fatty acid.

18. (Amended) A pharmaceutical composition according to claim 11 wherein the wax comprises at least one glyceride of a fatty acid having 12 to 18 carbon atoms.

19. (Amended) A pharmaceutical composition according to claim 11 wherein said composition comprises about 20 to 30% by weight of said wax, and less than 70% by weight of said active ingredient.

REMARKS

Reconsideration of the patentability of the claims of the instant patent application is solicited in view of the above amendments and the following comments. It is not believed that any extension of time or any fee is due with the filing of this response. However, if an extension is required to maintain the pendency of this application, kindly consider this to be a petition therefore. If any fee is due, kindly charge the same to the undersigned attorneys' deposit account 07-1337.

It is recognized that this application is under final rejection and that, after final rejection, the examiner has substantial latitude in entering or not entering proposed amendments. The above claim amendments are clarifying in nature and do not represent the addition of limitations that require the examiner to do any additional searching. The invention now being claimed is the same invention that was previously claimed, albeit in somewhat different words. The instant claims more

completely identify the differences between the instant claimed composition and the compositions of the prior art.

As the examiner has pointed out, an otherwise unpatentable composition does not become patentable by identifying a novel and unobvious use intended for that composition. In this case, the nature of the composition being claimed and the method of making the solid product that comprises that composition determine the properties of that solid product and those properties are the crux of the instant invention. Although prior workers have disclosed compositions that contain an active ingredient and a wax having a low melting point, these prior compositions contained other essential ingredients and/or were made in such a manner that they did not have the properties that are essential to the instant invention, namely not disintegrating in the mouth, disintegrating in lower portions of the gastrointestinal tract and enabling more effective amounts of the active ingredient to enter the ingestor's system by being released in a portion of the gastrointestinal tract that encourages passage of the active ingredient through the GI wall.

It has been found, and the instant specification clearly supports, that a smaller dosage of a specific active ingredient administered using the composition and structure of the instant claimed invention, is at least as effective as a larger dosage administered by disintegration in the oral cavity. While it is not totally understood why this should be the case, it is thought that when the active ingredient is released in the oral cavity, it is subject to attack in the stomach because of the inherently harsh conditions that prevail there. By contrast, if the active ingredient is protected until it passes substantially through the stomach into the intestine, and most of the active ingredient released there, more of the active ingredient passes into the blood stream in tact so that it can have its desired effect on the body. Therefore, a smaller amount released in the intestine is as, or more, effective than a larger amount released in the oral cavity.

Similarly, time release control can be effected in the intestine, according to this invention, by employing a combination of waxes with different melting points as the binder that holds the active ingredient in a solid dosage form until it is released in a controlled manner in the intestine In the prior art, cited by the examiner, the disclosed compositions all had the property of disintegrating in the mouth. Although they may have disclosed combinations of an active ingredient with a low

melting wax, there was always required some additional component of the composition or some manner of making the dosage form solid that enabled the solid to disintegrate in the oral cavity, rather than holding it together until it reached the intestine as required by the instant invention. The functional features of the instant claimed composition recited in the claims clearly distinguish the instant claims from the prior art. Therefore, the prior art disclosures do not render the instant claimed composition unpatentable either under an anticipation or obviousness theory.

The specific distinctions between the instant claimed composition and the compositions disclosed in the prior art will be more specifically discussed below. It is therefore urged that these amendments be entered at least for purposes of appeal as they at least obviate the anticipation rejections that have been made by the examiner, as will be clear from the following comments.

In the outstanding action, the examiner has objected to the introduction of claims 26-35 as being directed to a patentably distinct invention. The instant applicant disagrees with the examiner but, in order to expedite the prosecution of this application, these claims have been canceled without prejudice to the filing of one or more 1 applications directed to the subject matter thereof. The protection of 35 USC 121 is hereby asserted as a consequence of the examiner's refusal to examine claims 26-35.

In the outstanding office action, the examiner has again rejected the patentability of claims 11-25 as being anticipated by, or obvious in view of, the disclosure of the cited abstract of Japanese patent JP 8333243. These rejections are respectfully traversed and their withdrawal is solicited.

This reference discloses a tablet containing two distinct fractions that have been assembled together: a first granule comprising fats or oils and an excipiant; and a second granule that comprises an excipiant but no fats or oils. The excipiant must be a water soluble saccharide. The fats or oils are said to be solid at normal temperatures and have a 30 to 37°C melting point. These materials are illustrated by vegetable fats, such as corn oil, animal fats such as "cream" (this is undoubtedly a poor translation) and hard fats (whatever that may be). The examiner has

stated that the cited Abstract teaches that, in an example, Witepsol is disclosed as a fat or oil substance. The copy of the Abstract of JP '243 that applicants have does not say that. A copy of applicants' copy of this reference is attached for the examiner's consideration. If she has a different Abstract that does disclose the use of Witepsol as a fat or oil, it would be appreciated if she could FAX a copy to the undersigned attorney at the below referenced FAX number.

It is pointed out that this reference discloses that the water soluble excipient makes up 70 to 93 weight percent of the whole first granule and 85 to 90 weight per cent of the whole tablet, that is the combination of the first and second granules. The fats and oils make up 30 to 70 weight percent of the first granule, and 3 to 20 weight percent of the whole tablet. Thus, a major amount of the contents of the reference's tablet is a water soluble excipient. This is what provides the tablet with its rapid disintegration characteristic. No such major amount of water soluble excipient is required or desired in the instant composition. In fact, it would be a detriment because it would make the instant solid dosage form be disintegrated in the mouth, whereas the instant specification and claims clealry disclose that the instant composition is not disintegratable in the mouth to any appreciable extent.

In any case, even if Witepsol is disclosed to be one possible fat or oil, that still neither anticipates the instant claimed invention, nor renders it obvious. The reference tablet has a major amount of an excipient that is a water soluble material, such as a saccharide, as an essential component. This component is essential because as the excipient portion of the second granule, and the excipient portion of the first granule, dissolve in the aqueous environment of the oral cavity, the tablet disintegrates leaving the fat or oil and the active ingredient in a dispersed condition such that the active ingredient can dissolve in the oral cavity and cannot not be protected from the harsh conditions that prevail in the stomach.

In the reference, the excipient is there to enable disintegration of the tablet in the mouth. The reference does not say what the fat or oil is there for except to "obtain a fat or oil containing tablet rapidly disintegrating in the oral cavity". The property of rapid disintegration in the mouth, which is essential to the tablet of the reference and is provided by the major amount of water

soluble excipient, is antithetical to the instant claimed product, which does not "rapidly disintegrate in the oral cavity", and, in fact, does not disintegrate to any appreciable extent until it proceeds down the gastrointestinal tract to a region where the low melting wax is exposed to a temperature at which it melts. That certainly is not in the mouth. There is no disclosure in the instant specification of employing any water soluble excipient. The incorporation of a water soluble saccharide, or other ingredient that would cause the instant tablet to disintegrate in the mouth would be antithetical to the whole purpose of this invention, which is to maintain the integrity of the tablet until it gets further down the GI tract where the resident temperature will cause the low melting wax to melt and therefore release the active ingredient upon such melting, and not appreciably before.

The examiner has admitted that the reference does not teach the use of the disclosed composition in the same manner as applicants. However, the examiner has taken the position that, since the instant claims are composition claims, their intended use is not pertinent to patentability unless the intended use creates some structural difference. The examiner has posited that the instant intended use does not create a structural difference and therefore is not grounds for patentability, even if the reference does not disclose this same method of use. However, that is not so. The manner in which the instant product is made and its composition are essential to enable the intended use of this composition. The instant composition must be put up in solid form by compression or granulation, and it must be made up of the specified materials, so that it will **not** disintegrate in the mouth. In the Japanese reference, the disclosed product must be made in such a way that it will **rapidly** disintegrate in the mouth. These are completely antithetical. It is believed that the instant amended claims clearly establish the distinction between the instant invention and the disclosure of the Japanese abstract. Therefore, it is urged that the examiner withdraw this ground of rejection.

In the outstanding action, the examiner has rejected the patentability of all of applicants' claims as being either anticipated by, or at least obvious in view of, the disclosure of the cited Douglas et al. patent. The examiner has asserted that the reference teaches a tablet composition comprising an active agent and Witepsol. Presumably, the examiner is referring to Example 15

in column 9 of the reference. She has also specifically cited various portions of column 3 of the reference. It is agreed that these portions of the reference are the most pertinent disclosures relative to the patentability of the instant claimed invention.

In column 3, the reference states, "Cast chewable tablets may be prepared by incorporating the resin adsorbate in one or more low melting point fatty base(s) (e.g. triglyceride bases). In Example 15, the reference states that it is a Cast Chewable Tablet that is made by melting together Witepsol H15 and theobroma oil at 36°C; adding the rest of the solids (drug resinate, aspartame and flavor) to the molten mixture and then casting the molten mixture into the desired shape of a chewable tablet. The Witepsol represents 80 weight percent of the whole composition.

A chewable tablet is intended to disrupt and dissolve in the mouth. That is why the aspartame is there, so that the aqueous fluid in the oral cavity will dissolve it and thereby make the tablet easier to break up in the mouth and chew. In this respect, the chewable tablet of this reference is similar to the tablet of the Japanese reference. Further, note the reason for the invention of the Douglas et al. patent. It is to avoid the bitter taste of medicine in the mouth. IF the tablet is constructed so that it will pass through the mouth undisrupted and undissolved, there is no taste problem and therefore no reason for the Douglas et al. invention.

In evaluating the applicability of a reference, one must consider the reference as a whole. Merely taking a small piece of disclosure out of context is not appropriate. In this case, the disclosure of the tablet of Douglas et al. must be read to include whatever is needed to make the tablet disintegrate and dissolve in the mouth. In marked contrast, the instant claimed invention requires that the tablet not disrupt or dissolve, to any appreciable extent, in the oral cavity. Not only does the disclosure of the Douglas et al. patent not anticipate the instant claims, because the claims require both the proportion of ingredients and the manner of making the solid dosage form to cooperate to make the product pass through the mouth into the lower GI tract substantially in tact, which is exactly the opposite of what is described by Douglas et al., but that disclosure does

not render the instant claimed invention obvious, If anything, it lends patentability to the instant claims.

It is urged that the examiner carefully reconsider her position and withdraw the rejection of the patentability of the claims of this application based on the two applied references of record.

Respectfully submitted,

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not attached

ATTACH: Copy of Abstract of Japanese patent JP8333243

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MGG/vgg